AMENDMENTS TO THE SPECIFICATION

Please amend the paragraph starting on line 13 of page 40 with the following amended paragraph:

Alternatively, the above-described process can be performed as a continuous process wherein the step of disconnecting the inlet lumen 230 from the whole blood source 398 can be avoided. The continuous process separation of whole blood may be achieve by using a disposable centrifuge bag 226' as illustrated in Figures [39-39] 35-39 comprising an inlet tube 248 and three outlet tubes 245, 247 and 250, wherein the tubes are connected to an umbilical cable comprising four lumens. More specifically, a disposable centrifuge bag for use in a continuous separation of whole blood comprises inlet tube 248 connected via an inlet lumen to a whole blood source container, a first outlet tube 250 connected to a first outlet lumen that is in turn connected to a platelet rich plasma receiving container, a second outlet tube 245 connected via a second outlet lumen to either a red blood cell receiving container or a waste container and a third outlet tube 247 connected via a third outlet lumen to a platelet poor plasma receiving container. In the continuous separation process, after withdrawal of the portion of platelet rich plasma or other cellular components as described above with reference to Figures 33 and 34. Centrifuge bag has the capacity to receive an additional volume (aliquot) of whole blood. Consequently, as shown in Figure 35 infusion of an aliquot of whole blood is reinitiated through first inlet tube 248 with continued centrifugation until the capacity of the centrifuge bag 226' is reached. As a result of the additional volume of blood, the profile of the blood fractions in centrifuge bag 226' will approximately assume the profile shown in Figure 35. As can be seen in Figure 35, the additional volume of blood results in a shift of the location of the blood fractions, such that the platelet rich plasma fraction 260 has shifted back into the area of the bent fitting 252, and the platelet poor plasma fraction 262 has shifted back towards the inner perimeter 240 and away from the vicinity of the bent fitting 252. Additional platelet rich plasma 260 can now be removed from centrifuge bag 226' through outlet tube 250 as shown in Figure 35.

Please amend the paragraph starting on line 4 of page 58 with the following amended paragraph:

In the embodiment illustrated in Figure 53, the processing system 800 includes a blood source 802 connected with a fluid line 804 to an inlet pump 810. A valve 806, such as

a solenoid-operated valve or a one-way check valve, is provided in the fluid line 804 to allow control of flow to and from the blood source 802 during operation of the inlet pump 810. The inlet pump 810 is operable to pump blood from the blood source 802 through the fluid line 818 to a centrifuge [820] 20. Once all or a select portion of the blood in the blood source 802 have been pumped to a blood reservoir 824 of the centrifuge 820 the inlet pump 810 is turned off and the blood source 802 isolated with valve 806. The inlet pump 810 may be operated at later times to provide additional blood during the operation of the processing system 800 (such as during or after the removal of a separated component).

Please amend the paragraph starting on line 1 of page 59 with the following amended paragraph:

As discussed in detail previously, components of particular densities assume radial positions or belts at differing distances from the central axis A of the rotor 202. For example, the heavier red blood cells typically separate in an outer region while lower density platelets separate into a region more proximal to the central axis of the rotor 202. Between each of these component regions, there is an interface at which the fluid density measurably changes from a higher to a lower density (i.e., as density is measured from an outer to an inner region), and this density interface is used in some embodiments of the centrifugal processing system [10] 800 to identify the location of component regions (as will be discussed in more detail below). In a preferred embodiment, the drive assembly 822 continues to operate to rotate the centrifuge 20 to retain the separation of the components throughout the operation of the centrifugal processing system [10] 800.

Please amend the paragraph starting on line 26 of page 59 with the following amended paragraph:

A concern with fixing the radial distance or location of the outlet port is that each blood sample may have varying levels or quantities of different components. Thus, upon separation, the radial distance or location of a particular component or component region within the centrifuge bag 226 varies, at least slightly, with each different blood sample. Additionally, because of the varying levels of components, the size of the component region also varies and the amount that can be pumped out of the centrifuge bag 226 by the outlet pump 830 without inclusion of other components varies with each blood sample. Further, the position of the component region will vary in embodiments of the separation system [10] 800

in which additional blood is added after or during the removal of blood by the outlet pump 830.

Please amend the paragraph starting on line 5 of page 60 with the following amended paragraph:

To address the varying location of a particular separated component, the centrifugal processing system [10] 800 preferably is configured to adjust the location of a separated component to substantially align the radial location of the separated component with the radial location of the outlet port. For example, the centrifugal processing system [10] 800 may be utilized to collect platelets from a blood sample. In this example, the centrifugal processing system [10] 800 preferably includes a red blood cell collector 812 connected to the inlet pump 810 via fluid line 814 having an isolation valve 816 (e.g., a solenoid-operated valve or one-way check valve). Alternatively, the pump or syringe may also act as the valve. The inlet pump 810 is configured to selectively pump fluids in two directions, to and away from the centrifuge 820 through fluid line 818, and in this regard, may be a reversible-direction peristaltic pump or other two-directional pump. Similarly, although shown schematically with two fluid lines 804 and 814, a single fluid line may be utilized as an inlet and an outlet line to practice the invention.

Please amend the paragraph starting on line 1 of page 61 with the following amended paragraph:

To provide automation features of the invention, the centrifugal processing system [10] 800 includes a controller 850 for monitoring and controlling operation of the inlet pump 810, the centrifuge 20, the drive assembly 822, and the outlet pump 830. Numerous control devices may be utilized within the centrifugal processing system [10] 800 to effectively monitor and control automated operations. In one embodiment, the controller 850 comprises a computer with a central processing unit (CPU) with a digital signal processor, memory, an input/output (I/O) interface for receiving input and feedback signals and for transmitting control signals, and software or programming applications for processing input signals and generating control signals (with or without signal conditioners and/or amplifiers). The controller 850 is communicatively linked to the devices of the centrifugal processing system [10] 800 with signal lines 860, 862, 864, 866, and 868 which may include signal conditioning devices and other devices to provide for proper communications between the controller 850

and the components of the centrifugal processing system [10] 800.

Please amend the paragraph starting on line 14 of page 61 with the following amended paragraph:

Once blood is supplied to the blood source container 802, the operator pushes the start button and the controller 850 transmits a control signal over signal line 864 to the drive assembly 822, which may include a motor controller, to begin rotating the centrifuge 20 to cause the components of the blood in centrifuge bag 226 to separate into radially-positioned regions (such as platelet rich plasma regions). After initiation of the centrifuge spinning or concurrently with operation of the drive assembly 822, the controller 850 generates a control signal over signal line 860 to the inlet pump 810 to begin pumping blood from the blood source container 802 to the centrifuge bag 226 of the centrifuge 20. In some embodiments of the processing system 800, the drive assembly 822 is operable at more than one speed or over a range of speeds. Additionally, even with a single speed drive shaft the rotation rate achieved at the centrifuge 20 may vary. To address this issue, the processing system [10] 800 may include a velocity detector 858 that at least periodically detects movement of the centrifuge bag 226 portion of the centrifuge 20 and transmits a feedback signal over signal line 866 to the controller 850. The controller 850 processes the received signal to calculate the rotation rate of the centrifuge 20, and if applicable, transmits a control signal to the drive assembly 822 to increase or decrease its operating speed to obtain a desired rotation rate at the centrifuge bag 226.

Please replace the paragraph starting on line 1 of page 62 with the following amended paragraph:

To determine when separation of the components in the centrifuge bag 226 is achieved, the processing system 800 may be calibrated to account for variations in the centrifuge 20 and drive assembly 822 configuration to determine a minimum rotation time to obtain a desired level of component separation. In this embodiment, the controller 850 preferably includes a timer mechanism 856 that operates to measure the period of time that the centrifuge 20 has been rotated by the drive assembly 822 (such as by beginning measuring from the transmission of the control signal by the controller 850 to the drive assembly 822). When the measured rotation time equals the calibrated rotation time for a particular centrifuge 20 and drive assembly 822 configuration, the timing mechanism 856

informs the controller 850 that separation has been achieved in the centrifuge bag 226. At this point, the controller 850 operates to transmit control signal over signal line 860 to the input pump 810 to cease operation and to the outlet pump 830 over signal line 868 to initiate operation to pump a separated component in the component region adjacent the outlet port of lumen 232 of centrifuge bag 226 through fluid line 828. In another embodiment where rotation time is utilized by controller 850, the velocity feedback signal from the velocity detector 858 is utilized by the controller 850 to adjust the rotation time as necessary to obtain the desired level of component separation. For example, the centrifugal processing system [10] 800 can be calibrated for a number of rotation rates and the corresponding minimum rotation times can be stored in a look up table for retrieval by the controller 850 based on a calculated rotation rate. Rotational rates may be varied either manually or automatically to optimize cellular component position and or concentration.

Please amend the paragraph starting on line 4 of page 63 with the following amended paragraph:

The source and the detector of the sensor assembly 840 are preferably located within the centrifugal processing system 800 to allow monitoring of the centrifuge bag 226 and, particularly, to identify the presence of a particular blood component in a radial position coinciding with the radial position of the outlet port of the centrifuge bag 226. In one embodiment, the radiation beams from the source are transmitted through a "window" in the centrifuge bag 226 that has a radial location that at least partially overlaps the radial location of the outlet port. During operation of the centrifugal processing system 800, the feedback signals from the detector of the sensor assembly 840 allow the controller 850 to identify when a density interface has entered the window. This may occur for a number of reasons. [When] The change in density may occur when red blood cells are being removed by operation of the inlet pump 810 to remove fluid from the centrifuge bag 226 via the inlet tube 248. The change in density may also occur when a denser component is being added to the centrifuge bag 226 causing the particular blood component to be pushed radially inward. In the centrifugation of whole blood, this occurs when additional blood is added by operation of the input pump 810 and red blood cells collect in a region radially outward from the platelet region.

Please amend the paragraph starting on page 75, line 26 with the following amended paragraph:

First, as discussed in detail previously and depicted in Figure 61, platelet rich plasma 260 and/or platelet poor plasma 262 are formed by centrifuging a quantity of anticoagulated whole blood 396 that was previously drawn from the patient. The platelet rich plasma 260 is first drawn from the centrifuge bag 226 and into collection chamber 400. Collection chamber 400 is preferably a syringe, but any container that will not contact activate the collected fraction is acceptable. The platelet rich plasma 260 can be pumped via outlet pump [830] 803 (Figure 53) into a collection chamber 400 or the desired fraction can be drawn directly into dispenser 902.

Please amend the paragraph starting on page 78, line 11 with the following amended paragraph:

In an alternative embodiment, thrombin [950] 955 is mixed with the platelet poor plasma 262 of phase-two thereby forming the autologous platelet gel composition 972 of the present invention in less than three minutes.